

Remarks

The claims now pending are Claims 31-43, 48-53, 55, 60, 62, 67 and new Claims 68 and 69 are added. Claims 44 and 45 are canceled without prejudice.

The remarks below address first the rejections under 35 U.S.C. § 112, Second Paragraph, and thereafter the rejections under 35 U.S.C. § 103.

I. Rejections under 35 U.S.C. § 112, Second Paragraph

1. Claim Objections on Page 2, Paragraph 3 of the Office Action. The objections to Claims 48, 62 and 63 are overcome by correcting the typographical error of an added period "." has been deleted in each claim.

2. Claim Rejections under 35 U.S.C. § 112, Second Paragraph on Page 2, Paragraph 4 of the Office Action regarding Claims 39, 44-47, 55, 60 and 62-66.

A. Indefiniteness in Claim 39 is overcome by amendments to add positive recitation of "material with a reticular or laminar structure".

B. Rejection of Claim 46 and new claims 68 and 69 as indefinite is overcome by amendments which include appropriate antecedents and which recite certain dimensions of the new device as described in the specification on pages 4-5 and as shown in corresponding drawings in Fig. 1a. For example,

(1) total length of the device is the distance between labeled locations d and z,

(2) width of the trapezoid small base is the distance between locations labeled b and b,

(3) width of the trapezoid large base is the distance between locations labeled h and h;

(4) the distance between ends of front arms E, E is indicated by labeled locations a and a; and

(5) the distance between ends F, F of the rear arms is indicated by labeled locations i and i.

Also, in Claim 46 the dimension of hole U is the diameter represented by radii xy and xe, where xy = 0.6 to 1.6, and ye = 0.6 to 1.6, so that the diameter ye = 1.2 to 3.2 cm.

In view of the above amendments in Claims 46, 68 and 69 it is believed that the objections re insufficient antecedent basis are overcome.

C. Rejection of Claims 48-53, 60 and 62-66 Indefiniteness. The phrase "possibly tension free" is deleted by the current amendments to these claims. The feature of "tension free" is specifically recited in Claim 55.

D. Rejection of Claim 55 for insufficient antecedent basis. This is overcome by the amendment to make claim 55 dependent on method claim 48.

E. Further rejection to Claim 55 regarding an omitted essential step. This is overcome by amendments of adding steps.

F. The rejections of Claims 62-66 for insufficient antecedent basis. This is overcome by changing "the flat implantable device" to "a flat implantable device".

G. The further rejections of Claims 62-66 in the last paragraph of Page 4 of the office Action regarding the inappropriate portions of the Markush claim terminology. This is overcome by omissions of selected text as indicated.

H. The rejection on Page 5 of the Office Action of Claims 45, 47 and 60 as dependent on rejected Claim 46. This is believed moot, in view of the above-discussed amendments to Claims 44 and 46.

II. Rejections on Prior Art

All pending claims 31-66 have been rejected under 35 U.S.C. § 103(a): (1) as obvious over Landgrebe et al. in view of Rehil, or (2) as obvious over Landgrebe et al. in view of Rehil and one or more additional prior art references.

It is respectfully submitted that all the rejections based on the primary prior art reference to Landgrebe et al. will be overcome, and thus the other rejections based on still additional prior art will be moot. Accordingly, the Remarks at this time will focus on Landgrebe et al.

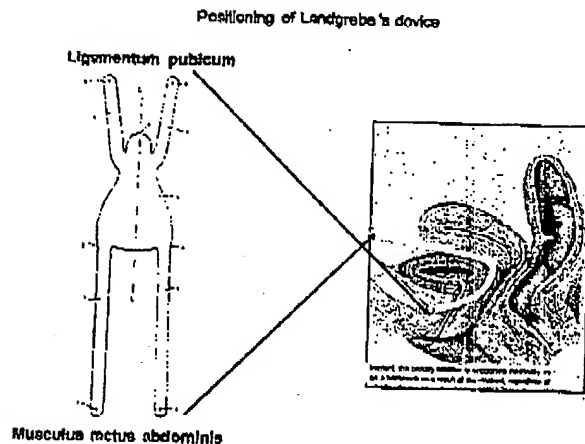
Landgrebe et al. is cited for disclosing all the elements (or steps) of the present device claims and method claims respectfully, except for the hole and cleft disclosed by Rehil. It is respectfully submitted that the Remarks below will demonstrate (a) that Landgrebe et al. fails to disclose numerous material and critical features of the present

invention, (b) that Landgrebe et al. is intended for a totally different object and function, (c) that Landgrebe et al cannot be used or useful in the field of the present invention, and (d) that Landgrebe et al. even if modified or combined with Rehil will not and cannot meet the present claim limitations, and (e) finally that based on the above, there is no teaching, suggestion or motivation in Landgrebe et al. or Rehil to reasonably combine them as proposed in the present rejections.

In the first place it is believed that the disclosure in Landgrebe et al. is misunderstood and consequently the various assertions in the rejections are believed to be erroneous.

Discussion of the Disclosure in Landgrebe et al.

A first misunderstanding of Landgrebe et al. is about the final position of the device in the female pelvis. The illustration below shows the positioning of Landgrebe's device (see col. 3 lines 35-38, lines 57-60):



It is evident that it can only hold bladder (and urinary bladder, see col. 1 lines 40-42, 53-54), but not any other female pelvic organ (uterus and/or enterocele which are never mentioned by Landgrebe and evidently are not supported by the therein described device). This device of Landgrebe is only suitable for the surgery treatment of urinary incontinence (devoid of pelvic prolapse) and at most (when the pelvic floor is still functional and the uterus is still in its correct anatomical position) correct cystocele (that is the prolapse of bladder only, this pathological condition is also called partial prolapse).

The rejection states that Landgrebe's device is "for supporting female pelvic organs"; however, Landgrebe et al. has a far more limited objective, namely, suspension of the urinary bladder (Column 1, lines 3-5, and "to provide an implant for reliable treatment of incontinence of urine in women" (Column 1, lines 33-35).

The device of Landgrebe et al. has a shape (triangle like or elongated oval) and the bridle-like projections (5,6 and 7,8) which are suitably designed for supporting "elastically as on an hammock the urinary bladder" (see col. 2 lines 53-54) and for being anchored two projections at ligamentum pubicum the other two projections at the muscle rectum abdominis.

Projections 7 and 8 are essentially opposite in direction (downwards) with respect to projections 5 and 6 (upwards) (see Fig. 1 and col.2, lines 48-51). Projections 7 and 8 are essentially parallel each other (see figure 1 and col. 2 lines 51-54) and are longer than projections 5 and 6 (see claim 4).

Projections 5 and 6 are essentially parallel with respect to the longitudinal axis L-L and start at a certain distance from the corner 2 (see col. 2 lines 36-44). It is therefore evident that the two projections 5 and 6 are essentially parallel each other and are directed upwards (or at most each slightly diverging of a 20° angle from the longitudinal axis L-L, see col. 2 lines 38-44), but for certain they cannot be seen as coaxial.

In geometry, **coaxial** means that two or more forms share a common axis. The rejection states that these two arms are coaxial when the device is folded in half longitudinally. It is respectfully submitted that this assertion is incorrect, and that such is a proposed alteration or conversion without reasonable basis, and in fact would result in a non-usable device for Landgrebe or for applicant. If the device is folded in half longitudinally, firstly it is no use for supporting the bladder, and anyway the two arms (which are arranged in mirror symmetry to the longitudinal axis L-L, see col. 2 lines 41-44) when folded are superposed one upon the other becoming parallel and projecting in the same direction, and thus are not coaxial. Even if flat, Landgrebe's device has a certain thickness (i.e. at 0.07 mm, see col. 3, lines 12-14), and therefore it cannot be treated as if as a theoretical geometric shape on an ideal plane (whose thickness is ideally zero).

Important in Landgrebe's device is the presence of a semicircular to oval extension positioned between projections 5 and 6; this is needed for supporting the bladder neck (see claim 5, col. 6 lines 1-7).

Furthermore, it should be noted that Landgrebe's device is unidirectionally extendable in length (longitudinally) (see col. 3, lines 50-51). This is because it has to allow filling and emptying of the bladder. Therefore Landgrebe is silent about:

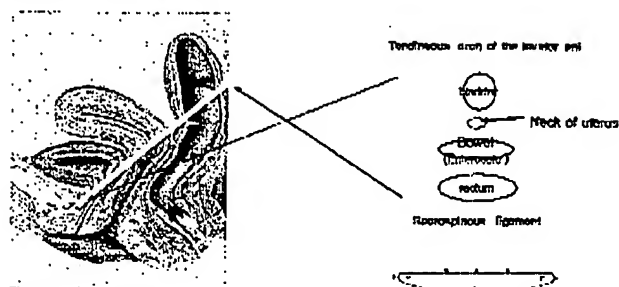
- shapes of the central portion of the device (base 1) other than triangle-like or oval elongated;
- disposition of the projections (5 and 6, 7 and 8) at angle higher than 20° with respect to axis L-L;
- disposition of projections 5 and 6 in a manner that they do not result to go in opposite directions with respect to projections 7 and 8;
- anchoring points of the projections other than ligamentum pubicum and muscle rectum abdominis;
- about a possible hole in the central portion of the device (such an hole would have been detrimental or of non-use in Landgrebe device).

THE PRESENTLY CLAIMED DEVICE

The present invention is further described and illustrated below, particularly positioning of this device in the female pelvis:

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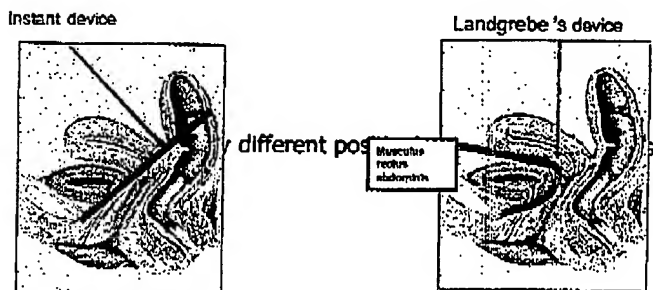
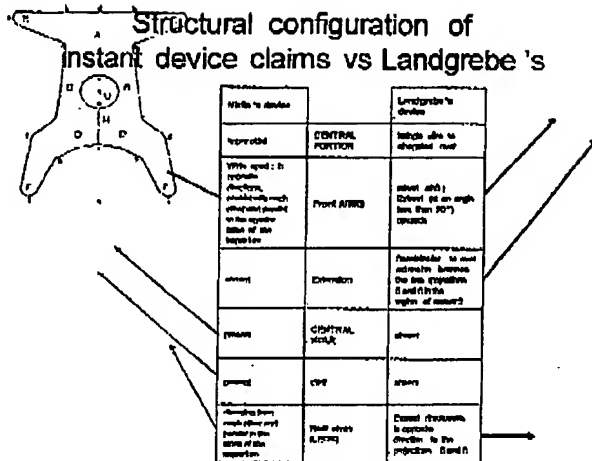
Positioning of instant device



The two front arms of the device (i.e. arms E) branch off the smaller base of the (isosceles) trapezoid body of the device. These arms are coaxial and parallel to the smaller trapezoid base and extend in opposite directions. These arms become fixed at the tendineous arch of the levator ani (one at right side and the other at left side). The two rear arms of the device (i.e. arms F) branch off the larger base of the trapezoid body. These arms are divergent from each other and generally parallel to the slanting sides of the trapezium, and become fixed at the sacrospinous ligament.

It should be now evident that the positioning of the present invention is completely different from that of Landgrebe device. By positioning as above represented, the new device has been designed, with the included hole of suitable dimension, for surrounding the uterus, with said hole suitably positioned in the central portion of the trapezoid body and a cleft suitable for allowing, during surgery, an easier the positioning of the device and its hole around the uterus.

PRESENT INVENTION vs. LANGREBE



From the above structural and functional differences it is evident that the present invention differences go well beyond the simple presence of a hole and a cleft.

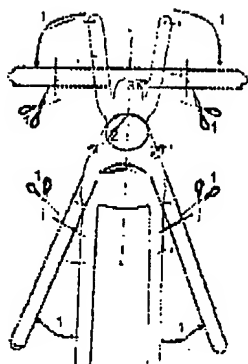
In Landgrebe the central portion of the device is called "base 1", and it clearly refers to the triangle-like central portion of the device. The present claims recite the word "base" meaning the two parallel edges of the trapezoid (i.e. in geometry the smaller or minor base and the larger or major base). Thus, the term "base" in the present claims is totally different from the term "base" used in Landgrebe et al.

In addition to all the structural differences and different objects between the present invention and Landgrebe, it is requested, merely for the sake of argument, that a surgeon attempts to use Landgrebe's device for anchoring it in the pelvis at the same four anchoring points of the instant device (which were anyway not mentioned at all by Landgrebe).

Landgrebe's device cannot be used in place of the present invention. Several and material modifications (would be required, far more than the simple addition of a hole and a cleft).

1. arms and legs would have to be shortened and moved wide apart (more than 20° from the longitudinal axis L-L), probably producing folds or overtension at the branching-off points thus weakening their holding capability;
2. A hole has to be made in the triangle-like central portion;
3. the extension in the region of corner (2) has to be cut away otherwise the bladder neck or the urethra could have been strangulated by this extension;
4. the base (i.e. geometry speaking the lower side) of the triangle-like portion (side between projections 7 and 8) has to be modelled for being suitably shaped (from convex to concave) to avoid strangling the rectum.

These speculative modifications are illustrated in the drawing below with dashed lines to show how the Landgrebe et al. device would have to be reconstructed.



It is respectfully submitted that many modifications cannot be considered obvious under 35 U.S.C. § 103.

COMBINATION OF Landgrebe with Rehil

The Applicant remarks that this combination is not feasible because there are no hints nor suggestions in Landgrebe nor in Rehil to combine them.

In the medical fields different anatomical regions have so many different peculiarities due to completely different physiology, that if there is not a clear hint from a document to another which refers to a completely different anatomical compartment, such a combination of documents is not inherently obvious. The simple fact of being related to the medical field is not enough for being combined.

All the more Rehil discloses a device which is not suitable for supporting the load of organs, but at most is useful for preventing organs from rising. It should be clear that a teaching for preventing something to rise is not suitable for preventing something to fall. If a hole of Rehil were added to the Landgrebe device which is

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designed for preventing the bladder from falling down, the result would allow the bladder to fall in the hole, thus defeating the object of Landgrebe et al. Therefore the teaching of Rehil would have never been obvious for combination.

Additionally, Landgrebe is silent about other possible anchoring points for the therein described hammock for the bladder.

It is noted with appreciation that claim 67 has been allowed. It has recently been discovered that this allowed claim has two inadvertent typographical errors: namely: (a) in the last paragraph, after "said method comprises: making an incision extending from the front vaginal wall to the", "cervix" should be replaced by "rear vaginal wall", and (b) in the last line the phrase "neck of the uterus" should be replaced by "sacrospinous ligament or to the iliococcygeal muscle." These corrections are made in the above amendments to the claims, and it is requested that the Examiner still find this claim allowable.

Respectfully submitted.

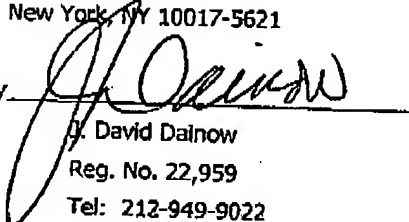
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